TRAINEE SECTION

Pendar Farahani MD, MSc, DABIM, FACP

Assistant Professor of Medicine, Public Health Sciences and Biomedical and Molecular Sciences, Division of Endocrinology and Metabolism, Queen's University
Attending Physician, Kingston General Hospital and Hotel Dieu Hospital

Challenges in Pharmacotherapeutics Education for Diabetes in Real-World Clinical Settings: Views From Family Medicine and Internal Medicine Residents

Abstract

Purpose: Pharmacotherapy for diabetes in real-world clinical settings is very complex and is posing a challenge for residents in training. The purpose of this study was to explore the views of residents in Canada regarding educational priorities for pharmacotherapy in diabetes management.

Methods: A questionnaire was developed to explore different domains of pharmacotherapy in diabetes management, including different clinical settings, combination pharmacotherapy with different classes of medications and patients' characteristics, including comorbidities and cardiovascular risk factors. The questionnaire and the letter of invitation was sent to residents through their program directors. The results were gathered through an online survey system. Due to the study design, response rate could not be determined. For data analysis, SPSS Software was used for statistical analysis. Chi-square testing was utilized for comparisons of proportions.

Results: Thirty-four residency programs in Canada were contacted and 165 residents completed the study. A significant number of the residents (59%) viewed combination pharmacotherapy for diabetes management as the most important educational priority ($p < 0.001$). Regarding insulin therapy, combination of insulin with another class of agents was recognized as the most important educational priority by 51% of residents ($p < 0.001$). Among all classes of medication for blood glucose management the education on the use of newer class of medication such as GLP1 agonists, DPP4 inhibitors and SGLT2 inhibitors was recognized as a priority by 77% of residents ($p < 0.001$).

Conclusion: This study provides new data and insights into residents' views on diabetes pharmacotherapy. Educational curriculums may incorporate these views from residents on the educational priorities that were identified in this study.

Correspondence to:

Pendar Farahani
Queen's University
94 Stuart Street, Kingston, Ontario
K7L 3N6, Canada
E-mail: pendar.farahani@queensu.ca

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Diabetes is a chronic disease with high incidence and prevalence, significant burden of illness due to complications, and high cost to society [1-3]. An estimated 285 million people worldwide are affected by diabetes [3]. With a further 7 million people developing diabetes each year, this number is expected to hit 438 million by 2030 [3]. More than 9 million Canadians live with diabetes or pre-diabetes [1,4,5]. In 2008/09, close to 2.4 million Canadians aged one year and older were living with diagnosed diabetes [4,5]. By 2020, it is estimated that diabetes will cost the Canadian healthcare system \$16.9 billion a year [5,6]. The main goal in clinical practice for management of diabetes regarding blood glucose, lipid and blood pressure is to achieve predefined goals according to the practice guidelines by applying non-pharmacological (lifestyle modifications) and pharmacological approaches to reduce the burden of illness and complications due to diabetes [1,2,7].

Currently, more than 10 classes of medication are available for treatment of hyperglycemia [1,2,7] and more molecules and classes of medication are becoming available for clinical practice in the future [8,9]. Each class of medication has its own advantages and disadvantages from an efficacy and safety profile perspective [1,2,7]. Furthermore, several classes of medication for lipid and blood pressure management in diabetes care are available [10,11] and the understanding of combination pharmacotherapy regimen will become more multifaceted [7].

In this milieu, individualized and patient-centred pharmacotherapy for diabetes is becoming more complex than ever before [7]; therefore, there is a need to teach principles of rational prescribing to residents [12] to enhance individualized and patient-centred pharmacotherapy for diabetes. Rational prescribing refers to the selection of the most appropriate therapeutic regimen for a specific patient [12]. Teaching rational prescribing is a crucial component of the training for residents [12]. A rational approach to choosing pharmacotherapy requires an enhanced knowledge of the pathophysiology, current treatment options and clinical guidelines for diabetes and its related conditions [13,14].

Several studies investigated knowledge gaps for healthcare providers, including residents, regarding pharmacotherapy and rational prescribing [15-18]. Such knowledge gaps in treating physicians can significantly impact diabetic patients; in a previously published study, a total of 856 diabetic patients were evaluated for pharmacotherapy-based problems [16]: 41.66% risks of potential drug interactions, 7.93% of adverse drug reactions and 6.6% mismatches were recorded [16]. Another study found that 70% of medical students and residents do not always assess potential drug-drug interactions before prescribing [15].

The objective of this study was to explore the views of residents in family medicine and internal medicine programs in Canada regarding educational priorities for diabetes pharmacotherapy in different domains including different clinical settings, combination pharmacotherapy of different classes of medications and patients' characteristics including comorbidities and cardiovascular risk factors.

Methods

A questionnaire (Appendix 1) was developed with questions addressing diabetes management in the inpatient, outpatient and preoperative settings, various classes of medications and the management of diabetic patients with comorbidity. Combination therapy and classes of medication for diabetes management were also examined. Furthermore, patients' characteristics impact on pharmacotherapy, such as comorbidities and cardiovascular risk factors management in diabetes, were explored. This questionnaire was novel and was not validated. Eight questions addressed the aforementioned domains and each question had three options; residents could choose only one option out of the three. There was no section for comments. The study received approval of the Ethics Committee at Queen's University. The study was uploaded to the "Survey-Monkey" system. A letter of invitation was sent to the directors of the accredited programs for internal medicine (17 programs) and family medicine (17 programs) in Canada requesting the participation of residents in their core training (PGY1-3 for internal medicine and PGY1-2 for family medicine). The results were gathered through the online survey system from the residents.

This survey was completely anonymous and voluntary; hence, researchers could not contact program directors to determine participation of residents for this study. After the program directors received the letter of invitation, it was their independent decision whether to send the invitation letter to the residents at their own programs or not. There is no information on how many programs sent the questionnaire to residents and as a result researchers could not calculate the number of residents who received the invitation and this is one of the limitations of this study: there is no data on the expected number of respondents or the numbers of programs that participated in this study. Due to this limitation, a power analysis was conducted with the target sample sizes for 120 and 150 participants. With assumption of type I error at 0.05 and a difference of 15% for proportions, a power of 89% and 94% were calculated for sample sizes of 120 and 150 participants, respectively. With the same assumption for type I error and a difference of 10% for proportions, a power of 64% and 73% were calculated

for sample sizes of 120 and 150 participants, respectively. A difference of 15% for proportions was considered to be significant, as this could provide sufficient power for a sample size of 150 or larger.

For data analysis, SPSS Software was used for statistical analysis. Chi-square testing was utilized for comparisons of proportions. The null hypothesis was that in each question, there was no differences amongst proportions of responses to the three options within each question and a distribution of 33.33% of response for each option in each question was expected. The analysis was conducted for the total cohort including both family medicine and internal medicine together. No statistical comparisons were made between family medicine residents versus internal medicine residents due to small sample size issues.

Results

Thirty-four residency programs in Canada were contacted and 165 residents participated and completed the questionnaire: 107 residents from family medicine (FM) and 58 residents from internal medicine (IM). In the total cohort, residents were primarily PGY1 (45%) and PGY2 (42%) as core years for family medicine residency programs in Canada include PGY1 and PGY2 but not PGY3. In addition, 13% of the residents were PGY3. The domains of the questionnaire and results of the study are tabulated at Table 1. The results are illustrated for the total cohort (for both family medicine and internal medicine disciplines, combined) with statistical analysis outcomes (p-values). Also, the numbers (N) of family medicine and internal medicine residents' selections for each option of each question are reported separately in Table 1.

A significant number of participants (68%) viewed outpatient pharmacotherapy in diabetes management as their educational priorities. For inpatient settings, management of blood glucose in medical ward, including severe hypoglycaemia, was recognized as an education priority by 47% of the cohort. Furthermore, combination pharmacotherapy for diabetes management in outpatient setting was viewed as the most important educational priority (59%) by residents. For preoperative settings, changing insulin regimen was recognized as an educational priority by 46% of residents. Management of blood glucose in diabetes was chosen by most residents (63%) as the most important issue to be addressed in their training compared with other cardiovascular risk factors, including dyslipidemia and hypertension. Most residents (75%) viewed education on pharmacotherapy for patients with diabetes and Chronic Kidney Disease (CKD) as the most important issue compared with diabetes with other comorbidities, including

Congestive Heart Failure (CHF) and Coronary Artery Disease (CAD). Among all classes of medications for blood glucose management, the education on the use of newer classes of medications, such as GLP1 agonists, DPP4 inhibitors and SGLT2 inhibitors, was recognized as a priority by 77% of residents. Regarding insulin therapy, combination of insulin with another class of agents was recognized as the most important educational priority by 51% of residents.

Discussion

A residency program should provide all the training components on pharmacotherapy in diabetes management, including the availability of comprehensive pharmacotherapy experiences both for inpatient and outpatient settings, counseling patients with diabetes for safety and effectiveness of pharmacotherapy and interpretation and application of pharmacokinetic data and principles to patient care [19]. The questionnaire for this study included questions for exploring different domains of pharmacotherapy in diabetes management, including different clinical settings, combination pharmacotherapy of different classes of medications and patients' characteristics including comorbidities and cardiovascular risk factors.

Setting of therapy and transition of pharmacotherapy

Medical care data indicated that most patients who seek medical care receive community-based outpatient care [20]. This may also be applicable specifically for patients with diabetes who seek medical care. The global epidemic of diabetes and its complications can signify the importance of diabetes care patterns in society [3]. An estimated 285 million people worldwide are affected by diabetes [3]. With a further 7 million people developing diabetes each year, this number is expected to hit 438 million by 2030 [3]. In the United States 25.8 million people (8.3% of the population) have diabetes [21]. In 2008/09, close to 2.4 million Canadians aged one year and older were living with diagnosed diabetes [4] and more than 9 million Canadians live with diabetes or pre-diabetes [5]. The results of the present study illustrates that a significant number of residents who participated viewed pharmacotherapy for diabetes management at outpatient settings as one of their educational priorities. Further, combination pharmacotherapy was highlighted as a particular focus.

Fast paced environments, such as those for outpatient to inpatient transitions or in preoperative care settings, require multifaceted changes in pharmacotherapy regimens [22,23]. An outpatient therapeutic regimen may no longer be appropriate in an inpatient setting for a variety of reasons. Stress can

TABLE 1. The questions, options and results of the study

Domains of questions	Options	(Total) Cohort %	P-Value	(FM) N	(IM) N
In your opinion, regarding diabetes management, what do you find the most challenging to get priority in your educational curriculum?	Inpatient diabetes management	24%	0.0001	17	22
	Outpatient diabetes management	68%		87	26
	Preoperative diabetes management	8%		3	10
In your opinion, regarding inpatient diabetes management, what do you find the most challenging to get priority in your educational curriculum?	Management of blood glucose in ICU including DKA or hyperosmolar state	36%	0.0006	41	19
	Management of blood glucose in medical ward including severe hypoglycemia	47%		59	19
	Management of blood glucose for preoperative patients	17%		7	21
In your opinion, regarding outpatient diabetes management, what do you find the most challenging to get priority in your educational curriculum?	Choosing the pharmacotherapy options for initial therapy	15%	0.0001	9	16
	Combination pharmacotherapy for diabetes	59%		62	34
	Initiation of insulin therapy for diabetes	26%		35	8
In your opinion, regarding preoperative diabetes management, what do you find the most challenging to get priority in your educational curriculum?	Changing insulin regimen for preoperative patients	46%	0.02	47	28
	Changing oral regimen for preoperative patients	27%		28	16
	Initiation of insulin therapy for preoperative patients	27%		30	14
In your opinion, regarding cardiovascular risk factors management for diabetes, what do you find the most challenging to get priority in your educational curriculum?	Management of lipid in diabetes	22%	0.0001	17	20
	Management of blood pressure in diabetes	15%		16	9
	Management of blood glucose in diabetes	63%		73	29
In your opinion, regarding diabetes patients with comorbidities, what do you find the most challenging to get priority in your educational curriculum?	Diabetes with CKD	75%	0.0001	78	46
	Diabetes with CHF	17%		19	9
	Diabetes with CAD	8%		10	3
In your opinion, regarding the classes of medication for blood glucose management in diabetes, what do you find the most challenging to get priority in your educational curriculum?	Use of insulin analogues	10%	0.0001	13	4
	Use of older class of medication such as sulfonylureas, biguanides and thiazolidinediones	13%		13	8
	Use of newer class of medication such as GLP1 agonists, DPP4 inhibitors and SGLT2 inhibitors	77%		81	47
In your opinion, regarding insulin use, what do you find the most challenging to get priority in your educational curriculum?	Initiation of insulin therapy	27%	0.0005	33	12
	Combination of insulin with other class of agents	51%		46	39
	Combination of insulin therapy as basal-bolus	22%		28	7

increase or decrease a patient's pharmacotherapeutics requirements [24]. Nutrition in the hospital may be different from that at home [24]. Medical conditions, such as hypotension, vasopressor use, edema, acute renal failure and surgical procedures, may alter medication requirements [24]. A previous study exploring residents' attitudes on inpatient diabetes management [22] confirmed that residents viewed inpatient hyperglycemia as highly prevalent and glucose control as important. Although the residents indicated that diabetes and hyperglycemia cases constituted a large proportion of their inpatient practices, these respondents expressed discomfort about management [22]. Knowledge deficits in the understanding of how best to apply insulin therapy were identified [22]. This issue has also been recognized by residents in the present study as an educational importance. The present study illustrates that for inpatient settings, management of blood glucose in medical ward, including for patients with severe hypoglycaemia, was recognized as an education priority by almost one-half of the cohort. Diabetes-related medical errors can lead to excessive morbidity, complications and mortality [25]. In the inpatient setting, errors involving insulin therapy have been associated with 33% of deaths that occurred within 48 hours of a medical error [26]. There is evidence that insulin errors can be reduced with educational curricula [27-29]. A pediatric residency program recently implemented a multifaceted, learner-centered diabetes curriculum due to resident diabetes-related inpatient errors [30]. Most errors were contributed to insulin use (43.8%). This educational approach resulted in a statistically significant decrease in diabetes-related inpatient errors from before intervention to after intervention and the study advocates for the implementation of such educational models across other medical disciplines [30].

Furthermore, glycemic control before, during and after surgery reduces the risk of infectious complications [31]; in critically ill surgical patients, intensive glycemic control may also reduce morbidity and mortality [32,33]. The preoperative assessment is important in determining risk status and determining optimal management to avoid clinically-significant hyperglycemia or hypoglycemia. While patients with type 1 diabetes should receive insulin replacement at all times, regardless of nutritional status, those with type 2 diabetes may need to stop oral medications prior to surgery and might require insulin therapy to maintain blood glucose control [31]. The present study illustrates that for preoperative settings, changing insulin regimen was recognized as an educational priority by almost one-half of residents. In a research study, an educational intervention to overcome clinical inertia in management of postoperative patients with diabetes led to greater utilization of

basal-bolus insulin therapy and improved glucose control without increasing hypoglycaemia [34]. The proportion of glucose values >180 mg/dL was lower during the intervention period than in the control period (21% *vs.* 31% of measurements), whereas the proportion of patients with hypoglycemia (i.e., glucose <70 mg/dL) was comparable.

Pharmacotherapy in diabetes with comorbidities and global cardiovascular risk reduction

Each year more patients with diabetes present with medical comorbidities and complications [35], both in elder and younger diabetic populations. A Chinese study found that patients with young-onset diabetes had a similar or worse metabolic risk profile compared with those with late-onset diabetes [36]. This group had higher risks for cardiovascular and renal complications at any given age, driven by longer disease duration [36]. As an example, CKD as a comorbid condition is associated with diverse alterations in carbohydrate and insulin metabolism. CKD state should be considered when treating diabetic patients, to ensure the introduction of adequate therapy adjustments that are in line with the onset of renal function decline. Moreover, several specific therapies employed in CKD may also influence pharmacological therapy of diabetes in uremic patients [37]. In elderly patients with CKD, blood glucose control targets and medication use should be individualized, based on factors such as life expectancy, renal function, hypoglycaemia risk and comorbidity [38]. As CKD is becoming more common in patients with diabetes [39,40], educational efforts should be tailored to address the residents' needs. CKD was identified by residents in the present study as the most challenging comorbidity in diabetes population for pharmacotherapy. Most residents view education on pharmacotherapy in patients with diabetes and CKD as the most important issue, compared with diabetes with other comorbidities including CHF and CAD.

Cardiovascular disease is the leading cause of death in patients with diabetes mellitus and represents a persistent risk that is inextricably linked to the diabetic disease state [41]. Diabetes is a disease of glucose metabolism that commonly involves multiple comorbidities, including lipid disorders and hypertension. Each concurrent disorder contributes some risk of complications and requires therapeutic intervention. The simultaneous management of so many coexisting illnesses can be complex and commonly results in patients being prescribed multiple medications (polypharmacy) which may further complicate treatment. To ensure the best patient outcomes, the treating physician must be aware of all the therapeutic agents that a patient is taking to assess possible drug interactions [42].

Proper glycemic control and attainment of other non-glycemic management targets including blood pressure and lipids are essential for the prevention of long-term complications of diabetes; therefore, patients with diabetes should be followed closely to ensure that they achieve and maintain treatment goals [43]. Nevertheless, in the present study pharmacotherapeutic management of blood glucose in diabetes was recognized by most residents as the most challenging issue to be addressed in their training compared to other cardiovascular risk factors including management of dyslipidemia and hypertension.

Combination pharmacotherapy and different classes of medication for blood glucose management in diabetes care

The growing number of approved antidiabetic agents provides a wide range of therapeutic options, both as monotherapy and combination therapy, for treating hyperglycemia in patients with diabetes [41]. The present study demonstrates that with the advancement in diabetes therapeutics and with the advent of new classes of medications, the complexity of pharmacotherapy, particularly as combination therapy, is becoming more important for residents. Treatment of type 2 diabetes mellitus often requires combinations of anti-hyperglycemic medications with complementary mechanisms of action [44]; for example, most residents in the present study find combination pharmacotherapy, particularly for insulin and use of newer classes of medication, the most challenging educational issue. Newer classes of anti-diabetes medication, such as incretin-based therapies and SGLT2 inhibitors, have the potential to be used not only for monotherapy but also in combination with any of the existing classes of glucose-lowering agents, including insulin [45]. Combining incretin-based therapies with basal insulin provides complementary actions to improve glycemic control in diabetes management, for example [46]. Theoretically, incretin-based therapies are an alternative to bolus insulin for certain groups of patients, such as the elderly, where meeting HgbA1C targets must be balanced against the risk of hypoglycaemia [46]. The improvements in glycemic control may reduce the incidence of diabetes-related complications, and an incretin plus basal insulin regimen may reduce risk of hypoglycaemia [47,48]. The results of the present study demonstrate that among all classes of medications for blood glucose management, the education on the use of newer classes of medications such as GLP1 agonists, DPP4 inhibitors and SGLT2 inhibitors, was recognized as a priority by most residents. Regarding insulin therapy, as currently more than 10 classes of medications are available for the treatment of diabetes, combinations of insulin analogues with medication from other classes

are emerging in the field of diabetes care. These analogues are characterized by various clinical pharmacology properties that can be utilized in clinical practice to tailor insulin therapy for each patient with diabetes, individually [49]. In clinical practice, there are many clinical considerations that can influence the choice of basal insulin analogues for a patient. These clinical considerations, from clinical pharmacology perspective for basal insulin analogues, could include 'tenting', 'coefficient of variance', 'dose-dependent duration of action', 'volume-to-surface effect', 'steady-state', 'site of the injection' and 'time-interval of the injection'. The respondents to the current study recognized that the combination of insulin with other classes of antidiabetic medications was the most important educational priority for insulin therapy. Furthermore, most residents viewed combination pharmacotherapy for diabetes management in an outpatient setting as the most challenging educational priority.

In conclusion, although residents have been taught basic pharmacology in medical school, they need additional, comprehensive instruction in pharmacotherapy in order to develop rational prescribing habits. The main objective of the pharmacotherapy curriculum is to support the development of residents' pharmacotherapy knowledge and medication prescribing skills required for rational prescribing. The results of the present study, which are the views and opinions of residents in family medicine and internal medicine programs in Canada regarding pharmacotherapy issues related to diabetes care, can be utilized to develop the educational curriculum and to incorporate the needs of residents into the pharmacotherapy educational initiatives for diabetes care. This data can guide us to develop scenarios and educational modules to address each specific issue as was prioritized by residents.

This study provided new data and insight into residents' views on diabetes pharmacotherapy. This is the strength and the value of this study and it is the first of such data to be collected, analyzed and presented. In this context, this study is unique and novel, and provides new insight; however, the questionnaire has not been validated. The generalizability of this data was limited by the decision of program directors to send the letter of invitation to residents; therefore, due to the study design, response rate could not be determined. A smaller sample size for internal medicine residents compared with family medicine residents limited a statistical analysis by residency discipline.

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Conflict of Interests

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APPENDIX 1. The questions and options of the study

Domains of questions	Options
In your opinion, regarding inpatient diabetes management , what do you find the most challenging to get priority in your educational curriculum?	Management of blood glucose in ICU including DKA or hyperosmolar state
	Management of blood glucose in medical ward including severe hypoglycemia
	Management of blood glucose for preoperative patients
In your opinion, regarding outpatient diabetes management , what do you find the most challenging to get priority in your educational curriculum?	Choosing the pharmacotherapy options for initial therapy
	Combination pharmacotherapy for diabetes
	Initiation of insulin therapy for diabetes
In your opinion, regarding preoperative diabetes management , what do you find the most challenging to get priority in your educational curriculum?	Changing insulin regimen for preoperative patients
	Changing oral regimen for preoperative patients
	Initiation of insulin therapy for preoperative patients
In your opinion, regarding cardiovascular risk factors management for diabetes , what do you find the most challenging to get priority in your educational curriculum?	Management of lipid in diabetes
	Management of blood pressure in diabetes
	Management of blood glucose in diabetes
In your opinion, regarding diabetes patients with comorbidities , what do you find the most challenging to get priority in your educational curriculum?	Diabetes with CKD
	Diabetes with CHF
	Diabetes with CAD
In your opinion, regarding the classes of medication for blood glucose management in diabetes , what do you find the most challenging to get priority in your educational curriculum?	Use of insulin analogues
	Use of older class of medication such as sulfonylureas, biguanides and thiazolidinediones
	Use of newer class of medication such as GLP1 agonists, DPP4 inhibitors and SGLT2 inhibitors
In your opinion, regarding insulin use , what do you find the most challenging to get priority in your educational curriculum?	Initiation of insulin therapy
	Combination of insulin with other class of agents
	Combination of insulin therapy as basal-bolus